FEB - 3 2005 K041224

Summary of Safety and Effectiveness

Submitted by:
Joy Shuford
Foothills Industries
172 Lukfin Street
Marion, NC 28752

Date Summary Prepared:
December 6, 2004

Proposed Devices:
Surgical drapes and utility drapes

Classification Name: Surgical Drape and Drape Accessories

Comparison Devices:
Foothills Industries surgical drapes and utility drapes are substantially equivalent to surgical drapes and utility drapes currently marketed by 3M Steri Drape (K031287) and Alcon (K830822).

Description of Device:
Foothills Industries disposable surgical drapes and utility covers are devices made from natural and synthetic materials intended to be used by medical professionals as protective coverings.

Intended Use:
Foothills Industries disposable surgical drapes and utility covers are devices made from natural and synthetic materials intended to be used by medical professionals as protective coverings, such as patient covering to isolate a site for surgical incision from contamination and to cover accessories in the operating room.

These disposable single-use drapes are designed to be repackaged and sterilized before use by the user using a 100% EtO cycle that has been validated to achieve a SAL of 10-6 in accordance with ANSI/AAMI/ISO 11135:1994. Sterilization residual limits should meet the requirements of the ANSI/AAMI/ISO 10993-9:1995.

Technological Characteristics:
Foothills Industries surgical and utility drapes are made from the same materials and designs as other currently marketed surgical drapes. They provide the same absorbency, packaging, and other performance characteristics and are similarly labeled as disposable and non-sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Ms. Joy Shuford
Chief Executive
Foothills Industries, Incorporated
172 Lukin Street
Marion, North Carolina 28752

Re: K041224
Trade/Device Name: Foothills Surgical Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: January 19, 2005
Received: January 21, 2005

Dear Ms. Shuford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041224

Device Name: Foothills Surgical Drapes

Indications For Use:

Foothills Surgical Drapes are devices made from natural and synthetic materials intended to be used by medical professionals as protective coverings, such as a patient covering to isolate a site for surgical incision from contamination and to cover accessories in the operating room.

These disposable single-use drapes are designed to be repackaged and sterilized before use by the user using a 100% EtO cycle that has been validated to achieve a SAL of 10-6 in accordance with ANSI/AAMI/ISO 11135:1994. Sterilization residual limits should meet the requirements of the ANSI/AAMI/ISO 10993-9:1995.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041224

Prescription Use ___ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)